articles failed to bear adequate directions for use; 502 (l)—the *Steclin capsules* purported to be and were represented as a drug composed wholly or partly of a derivative of chlortetracycline, and they were not from a batch with respect to which a certificate or release had been issued pursuant to law; and 503 (b) (4)—the *Steclin capsules* and the *Altepose tablets* were drugs which were subject to the provisions of 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–27–55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

4762. Gray, white, and pink tablets containing, among other ingredients, amphetamine phosphate racemic, thyroid, atropine sulfate, and phenobarbital. (F. D. C. No. 35590. S. Nos. 64–264/6 L.)

INFORMATION FILED: 2–3–55, Dist. Alaska, against Prentiss George Jones, a pharmacist, Anchorage, Alaska.

CHARGE: On 9–2–53, a quantity of *gray, white, and pink tablets containing, among other ingredients, amphetamine phosphate racemic, thyroid, atropine sulfate, and phenobarbital*, was caused, after shipment in interstate commerce, to be held for sale in a small bottle which failed to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," contrary to the provisions of 503 (b) (4).

PLEA: Guilty.

DISPOSITION: 6–24–55. $50 fine.

4763. Ascoramide tablets and Denta-Serts. (F. D. C. No. 38181. S. Nos. 18–891 M, 18–899 M.)

QUANTITY: 33 btls. containing 100 *Ascoramide tablets* each and 1 btl. containing 100 *Denta-Serts* at Chattanooga, Tenn.

SHIPPED: On an unknown date, from Columbus, Ohio, by Warren-Teed Products Co.

LABEL IN PART: (Btl.) "100 C. T. Creased * * * Warren-Teed Tablets Ascoramide Each tablet contains: Nicotinamide 50 mg., Ascorbic Acid 50 mg., Lactose Q. S." and "100 C. T. * * * Warren-Teed Denta-Serts (Sulfanilamide with Chlorophyll Wedges) Each compressed wedge contains sulfanilamide 0.12 Gm. (2 grs.) with chlorophyll For local chemotherapeutic action as an aid in preventing infection and dry socket and to aid in healing."

LIBELED: 6–15–55, E. Dist. Tenn.

CHARGE: *Ascoramide tablets.* 502 (a)—the statement on the label of the article when shipped "for the treatment of deficiency conditions associated with Vincent's infection, gingivitis and bleeding gums" was false and misleading since the article was not an effective treatment for such conditions.

Denta-Serts. 503 (b) (4)—the article was a drug subject to 503 (b) (1), and, when shipped, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–25–55. Default—destruction.

*See also No. 4761.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4764. B-amino-complex (B-amino-BAC-complex or Unitone) tablets. (Inj. No. 267.)

COMPLAINT FOR INJUNCTION FILED: 9–28–53, S. Dist. N. Y., against Barrows Chemical Co., Inc., and Unitone Corp., both of New York, N. Y., and against Joseph Barrows, president of the corporations, to enjoin the interstate shipment of an article in tablet form known by the trade names of "B-Amino-Complex," "B-Amino-BAC-Complex," and "Unitone." Amended complaint filed on or about 10–30–53.

LABEL IN PART: "B-Amino-Complex [or "B-Amino-BAC-Complex" or "Unitone"] * * * VITAMINS Daily dose of 6 tablets contains: Vitamin B_1 (Thiamine Hydrochloride) 18.0 mg. Vitamin B_2 (Riboflavin) 27.0 mg. Niacinamide 180.0 mg. Vitamin B_6 (Pyridoxine Hydrochloride) 3.0 mg. High Potency Yeast 200.0 mg. Brewer's Type Yeast 200.0 mg. Inositol 60.0 mg. Choline Hydrochloride 60.0 mg. Panthenol (Equal to Cal. Pantothenate 30 mg.) 26.1 mg. AMINO ACIDS (Vitagenic Accelerators) as contained in Yeast Protein Enzymatic Hydrolysate 1.0 Gm. Fortified with Nucleic Acid 100.0 mg. Glutamic Acid 50.0 mg. Glycine 50.0 mg. Cysteine Hydrochloride 25.0 mg. DI AND TRI-VALENT MINERALS Iron (Ferric Citro Pyrophosphate Soluble) 28.8 mg. Copper (Copper Sulfate) 2.1 mg. Magnesium (Magnesium Sulfate) 5.9 mg. Zinc (Zinc Sulfate) 1.4 mg. Cobalt (Cobalt Sulfate) 1.3 mg."

CHARGE: The complaint alleged that the defendants were engaged in the business of manufacturing, distributing, and selling the above-mentioned article and that, for the purpose of explaining the uses of the article and promoting its distribution, the defendants caused the article to be accompanied by labeling consisting of leaflets entitled "Amazing Medical Discovery," "If Your Body Could Talk It Would Say," and "A Revolutionary Advance in Nutrition," placards entitled "Amazing Discovery Checks Deafness, Helps Restore Hearing, Clinically Tested—Come in For Free Booklet," "BAC," and "For the One in Five Who is Hard of Hearing," and publications entitled "Nutritional Guide Better Nutrition Better Health" and "Health and Nutrition News Spring Summer 1953."

The complaint alleged further that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of the article which was misbranded as follows:

502 (a)—the label of the article and the above-mentioned accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for deafness; that it was a new and amazing discovery and a revolutionary advance as a food supplement which, when used as directed, would supply an important quantity of protein; that it was needed to activate the eyes, ears, lungs, liver, intestines, muscles, brain, heart, stomach, kidneys, and the entire body; that it would supply vitamins, proteins, and minerals in the correct proportions, and balanced amounts to stimulate the body to work as nature intended; that it would endow the user with vibrant life, health, and energy; that it would enable the liver to convert more than normal amounts of carbohydrates into energy; that it would supply increased energy to the heart, lungs, muscles, liver, and other important organs; that it would supply missing enzymes necessary to carry on body functions, such as growth, repro-

*See also No. 4761.

duction, secretion, nerve conduction, muscular contraction, etc.; that it would transfer fatigue to quick energy, prevent and correct dysfunction in the energy conversion chemistry of body functioning; and that it would reactivate all enzyme systems necessary for healthy body functioning and would activate the body cells to function as nature intended;

502 (a)—the following statements in the accompanying leaflet entitled "If Your Body Could Talk It Would Say," namely, "'Unbalanced B. Vitamins May Be Dangerous' . . . says The Journal of the American Medical Association in an Editorial of September 1, 1945. They say further . . . 'Extensive scientific evidence has revealed that if B Vitamins are administered in other than balanced proportions they may create Vitamin Deficiencies rather than cure them' . . . still quoting the JAMA, the Editorial continues 'Many B-Complex preparations available to the physician and public today are definitely unbalanced . . . either too much thiamine or not enough riboflavin, niacin, or pyridoxine,'" were false and misleading since the quotations contained in such statements did not appear in an editorial in the September 1, 1954, issue of The Journal of the American Medical Association; and,

502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of deafness, which was the condition for which the article was intended to be used and for which it was offered in the accompanying labeling described above and in advertising matter.

The complaint contained also allegations concerning the misbranding of the article under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 22449.

DISPOSITION: 11-18-54. The defendants having consented to the entry of a decree, the court entered a decree of permanent injunction. The decree enjoined the defendants against introducing into interstate commerce the above-mentioned article or any similar article accompanied (1) by the above-mentioned leaflets and placards or (2) by any written, printed, and graphic matter representing that the article was a new and amazing discovery and a revolutionary advance as a food supplement which, when used as directed, would supply an important quantity of protein; that the article was needed to activate the eyes, ears, lungs, liver, intestines, muscles, brain, heart, stomach, kidneys, and the entire body; that it would supply vitamins, proteins, and minerals in the correct proportions, and balanced amounts to stimulate the body to work as nature intended; that it would endow the user with vibrant life, health, and energy; that it would enable the liver to convert more than normal amounts of carbohydrates into energy; that it would supply increased energy to the heart, lungs, muscles, liver, and other important organs; that it would supply missing enzymes necessary to carry on body functions, such as growth, reproduction, secretion, nerve conduction, muscular contraction, etc.; that it would transfer fatigue to quick energy, prevent and correct dysfunction in the energy conversion chemistry of body functioning; and that it would reactivate all enzyme systems necessary for healthy body functioning and would activate the body cells to function as nature intended; or (3) by written, printed, and graphic matter representing that the article would check, cure, or be an adequate and effective treatment for deafness or hard of hearing. The decree provided, however, that the defendants could introduce the article into interstate commerce if it was accompanied by written, printed, or graphic matter clearly limiting and describing the use of the article only as follows:

For cases in which the cause of deafness has been medically diagnosed as hearing nerve deafness due to carbohydrate metabolic disturbance as indicated by high pyruvic acid level in the blood (higher than 2 mg. per 100 cc. under basal conditions), this product may be of value when used in conjunction with other suitable treatment prescribed by your physician. A blood test is necessary to determine whether the level of pyruvic acid in the blood is high.

The decree further enjoined the defendants against introducing the article into interstate commerce unless it was accompanied by written, printed, or graphic matter which clearly stated and enumerated every disease, condition, symptom, and purpose for which the article was intended to be used and for which it was represented by any means to the public.

4765. Ovarian extract, corpus luteum extract, Pit-Ovarin, and anterior pituitary extract. (F. D. C. No. 37586. S. Nos. 14–603/6 M.)

QUANTITY: 66 vials of *ovarian extract*, 77 vials of *corpus luteum extract*, 91 vials of *Pit-Ovarin*, and 22 vials of *anterior pituitary extract* at St. Louis, Mo.

SHIPPED: Between 10–7–54 and 12–1–54, from Philadelphia, Pa., by National Drug Co.

LABEL IN PART: (Vial) "List #167 Multiple Dose Vial 15 cc. Ovarian Extract * * * Each cc. contains the water and alcohol soluble extractives derived from 40 grains of fresh Ovarian Glands with Chlorobutanol 0.5% * * * For intramuscular use in non-specific therapy," "List #80 Multiple Dose Vial 25 cc. Extract Corpus Luteum * * * Each cc. contains the water soluble extractives derived from 18 grains of Chlorobutanol * * * 0.5% Contains no known hormonal therapeutic activity. For Intramuscular Use In Ovarian Dysfunction," "List #283 Multiple Dose Vial 25 cc. Pit-Ovarin * * * Each cc. contains water soluble solids from 20 gr., fresh Whole Ovary and from 5 gr., fresh Anterior Pituitary gland with Procaine Hydrochloride 1% and Chlorobutanol * * * 0.5% For use in nonspecific therapy," and "List #118 Multiple Dose Vial 25 cc. Anterior Pituitary Extract * * * Each cc. contains the water soluble ingredients obtained from 18½ grains of fresh anterior pituitary lobe tissue with Chlorobutanol 0.5%."

LIBELED: 1–7–55, E. Dist. Mo.

CHARGE: 502 (a)—the statement on the label of the *corpus luteum extract* when shipped, namely, "For * * * Use In Ovarian Dysfunction," was false and misleading as applied to the article, which would be of no value in the treatment of ovarian dysfunction, and the label statements of such article "Contains no known hormonal therapeutic activity" and "For * * * Use In Ovarian Dysfunction" were misleading when considered together since they were mutually contradictory; and 502 (f) (1)—the labeling of all of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from that requirement.

DISPOSITION: 2–3–55. Default—destruction.

4766. Elemin vitamin and mineral tablets. (F. D. C. No. 37520. S. Nos. 5–566/7 M.)

QUANTITY: 6 cases, 24 retail cartons each, and 10 cases, 12 retail cartons each, at Milwaukee, Wis.

SHIPPED: Between 11–24–53 and 4–6–54, from Berkeley, Calif.